

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 1-2, 4-11, 13, 15, 17-19, 22, 28, 30-31, 34-37, 81-82, and 93-98 were pending in the application. Claims 81 and 98 have been amended. No new matter has been added. Claims 1-2, 4-11, 13, 15, 17-19, 22, 28, 30-31, 34-37, 81-82, and 93-98 remain pending in this application.

#### **Rejection of Claim 35 Under 35 U.S.C. § 112**

Claim 35 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant notes that what is required under 35 U.S.C. §112, second paragraph, is that those skilled in the art understand what is being claimed when the claims are read in light of the specification. *Orthokinetics v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ 2d 1081 (Fed. Cir. 1986). In the present case, the limitation recited in claim 35, when read in light of Applicant's specification and figures, would be clearly understood by those of ordinary skill in the art.

Claim 35 also stands rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Specifically, the Office Action states that the omitted steps are the steps discussing applying a catalytic metal colloid to the reaction site. The Office Action asserts that the method would require first contacting the analytes with a binding partner labeled with a catalytic metal colloid in order for the metal precursor of claim 35 to have its intended purpose. Applicant respectfully traverses.

As an initial matter, Applicant notes that a rejection, such as the present one asserting that a claim lacks an essential step or limitation, is properly made under 35 U.S.C. 112, first paragraph for lack of enablement (MPEP §2172.01 ). Therefore, the basis of the present rejection is believed to be improper.

Moreover, it is well established that a claim will fail as being non-enabled only if it omits matter *disclosed to be essential* to the invention as described in the specification or in other

statements of record. (MPEP §2172.01, emphasis added; see also MPEP §2164.08<sup>1</sup>). Nowhere is the step of contacting the analytes with a binding partner labeled with a catalytic metal colloid disclosed or suggested in Applicant's specification as being essential to the invention. Accordingly, even presuming that 35 U.S.C. §112, second paragraph is a proper basis for the rejection, which it is not for at least the reasons noted above, the rejection cannot be maintained.

The Office Action also asserts that the claims are indefinite because the metal precursor has no purpose without the step of first contacting the analytes with a binding partner labeled with a catalytic metal colloid. Applicant respectfully disagrees. In making these determinations, the Office Action points to several paragraphs from the present application where the use of a metal precursor is described. Applicant notes, however, that these teachings are merely examples of how a metal precursor can be used, and that the scope of the claims is not limited by such teachings. For instance, Applicant's specification at page 27, lines 11-13 states, "In addition to depositing metal on any metal colloids that may be associated with portion 140 of microchannel 120, the metal precursor may also be deposited on metal that has previously been electrolessly deposited on the gold-conjugated antibody." (Emphasis added.) This language is clearly permissive and does not require the step of first contacting an analyte with a binding partner labeled with a catalytic metal colloid before the use of a metal precursor. Certainly, one of ordinary skill in the art would understand that the use of a metal precursor does not necessarily require the use of a binding partner labeled with a catalytic metal colloid.

It appears that the Patent Office's basis for objection to claim 35 may be it believes that the claim reads broader than certain specific, exemplary compositions in Applicant's specification. However, claim breadth is not an appropriate basis for a rejection under 35 U.S.C. §112, second

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<sup>1</sup> "A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. §112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made *only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended*. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality." (Quoting MPEP §2164.08, emphasis added).

paragraph, so long as those of ordinary skill in the art would understand the scope of the claim in view of the specification. MPEP §2173.04; In re Miller , 441 F.2d 689 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, as in the present case, and if the Applicant has not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. §112, second paragraph.

Relevant to this rejection, Applicant also points out that the law does not require that claims be limited by the specific compositions or examples mentioned in Applicant's specification, so long as the claims are properly enabled by the specification. Claims can be, and typically are, broad enough to cover at least some embodiments not specifically exemplified in the specification. Indeed, "[t]o demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials in a process... would not serve the constitutional purpose of promoting progress in the useful arts." In re Goffe , 542 F.2d 564, 567 (CCPA 1976).

Applicant believes that claim 35 is definite and clear to those of ordinary skill in the art and, therefore, is in full compliance with 35 U.S.C. §112, second paragraph.

Accordingly, Applicant respectfully requests withdrawal of the claim rejection on these grounds.

Rejection of Claims 1-2, 4-11, 13, 15, 17-19, 28, 30-31, 34, 81-82, 93-94, and 96-98 Under 35  
U.S.C. § 103(a)

Claims 1-2, 6-11, 15, 17-19, 28, 94, and 96 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,488,894 to Miethe et al. (hereinafter, "Miethe") in view of U.S. Patent No. 5,268,147 to Zabetakis et al. (hereinafter, "Zabetakis").

With respect to independent claim 1, while the Office Action recognizes that a fluid substantially immiscible with the first and second fluids is not transferred from the vessel to a reaction site as recited in claim 1, the Office Action states that it would have been obvious to maintain separation of the reagents of Miethe by an immiscible fluid, as suggested by Zabetakis, in order to minimize any potential sample carryover and to maximize the accuracy of the sample

liquids analysis results. Applicant respectfully disagrees and believes that Miethe, in fact, *teaches away* from transferring an immiscible fluid from the vessel along with the fluid reagents. Column 6, lines 10-48 of Miethe in connection with Figs. 11-12 describes a device that is specifically designed to include a hydrophilic membrane to *prevent* hydrophobic fluids from being transferred to the outlet channel. (See also the description on column 4, lines 2-5 of Miethe, which states, “there is a hydrophilic membrane allowing only the reagents to pass but not the hydrophobic separating liquids or the gaseous separating volumes”.) Clearly, Miethe recognized an advantage of transferring only the reagents, but not hydrophobic fluids, to the outlet channel. Therefore, if one of ordinary skill in the art modified Miethe in view of Zabetakis in the manner asserted in the Office Action to meet this claim limitation, Miethe would be unsuitable for its intended purpose.

For at least these reasons, Applicant believes that one of ordinary skill in the art would not have combined Miethe in view of Zabetakis in the manner asserted in the Office Action. Therefore, claim 1 and the claims that depend therefrom, are patentable over the asserted combination of Miethe in view of Zabetakis.

Claims 30-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Miethe in view of Zabetakis as applied to claim 1 above, and further in view of U.S. Patent Publication No. 2002/0199094 to Strand et al. (hereinafter, “Strand”).

As described above, Applicant believes that one of ordinary skill in the art would not have combined Miethe in view of Zabetakis in the manner asserted in the Office Action. Furthermore, Strand does not remedy the deficiencies of the combination of Miethe and Zabetakis for independent claim 1. Therefore, independent claim 1, and claims 30-31 which depend therefrom, are patentable over the asserted combination of Miethe in view of Zabetakis and further in view of Strand.

Claims 4-5, 13, 93, and 97-98 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Miethe in view of Zabetakis as applied to claim 1 above, and further in view of U.S. Patent Publication No. 2002/0092767 to Bjornson et al. (hereinafter, “Bjornson”).

As described above, Applicant believes that one of ordinary skill in the art would not have combined Miethe in view of Zabetakis in the manner asserted in the Office Action. Furthermore, Bjornson does not remedy the deficiencies of the combination of Miethe and Zabetakis for independent claim 1. Therefore, independent claim 1, and claims 4-5, 13, 93, and 97 which depend therefrom, are patentable over the asserted combination of Miethe in view of Zabetakis and further in view of Bjornson.

Regarding independent claim 98, the Office Action states that Miethe teaches discharging two liquids from a device in a simple, precise chronologically defined and sequential manner into a reaction chamber without prior mixing of reagents. Applicant notes, however, that claim 98 recites the step of providing a first and a second fluid maintained separately from each other by a third fluid adjacent to and substantially immiscible with the first and second fluids, and the step of avoiding contact between the first and second fluids at least until after the fluids have been applied to the reaction site. Miethe does not teach this limitation. As described in column 6, lines 10-48 of Miethe in connection with Figs. 11-12, reagent volumes are separated in the device using gas bubbles or volumes of hydrophobic liquids, and a hydrophilic membrane 54 prevents hydrophobic volume 58 from passing across the membrane. Because hydrophobic volume 58 does not pass across the membrane, reagent volumes 38 and 40 (e.g., “first” and “second” fluids) *necessarily* contact one another while in outlet channel 24. Thus, the step of avoiding contact between the first and second fluids, at least until after the fluids have been applied to the reaction site, is not met.

Furthermore, one of ordinary skill in the art would not have modified Miethe in view of Zabetakis in the manner asserted in the Office Action to meet this claim limitation, e.g., by maintaining separation of the first and second fluids by an immiscible fluid by removing the hydrophilic membrane, since this would render Miethe unsuitable for its intended purpose. Moreover, Bjornson does not remedy the deficiencies of the combination of Miethe and Zabetakis for independent claim 98 prior to its amendment herein. Therefore, independent claim 98 is patentable over the asserted combination of Miethe in view of Zabetakis and further in view of Bjornson.

Claim 34 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Miethe in view of Zabetakis, as applied to claim 1 above, and further in view of U.S. Patent Publication No. 2002/0001818 to Brock (hereinafter, "Brock").

As described above, Applicant believes that one of ordinary skill in the art would not have combined Miethe in view of Zabetakis in the manner asserted in the Office Action. Furthermore, Brock does not remedy the deficiencies of the combination of Miethe in view of Zabetakis for independent claim 1. Therefore, independent claim 1, and claim 34 which depends therefrom, is patentable over the asserted combination of Miethe in view of Zabetakis and further in view of Brock.

Claims 81-82 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bjornson in view of Miethe.

Miethe does not teach each claim limitation of independent claim 81 for at least the reasons described above with respect to claim 98. Furthermore, Bjornson does not teach the limitations missing in Miethe for independent claim 81 prior to its amendment herein. Therefore, Applicant believes that independent claim 81, and claim 82 which depends therefrom, is patentable over the asserted combination of Bjornson in view of Miethe.

Accordingly, Applicant respectfully requests withdrawal of the claim rejections on these grounds.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825, under Docket No. H0498.70219US02, from which the undersigned is authorized to draw.

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Respectfully submitted,

By \_\_\_\_\_/Timothy J. Oyer/  
Timothy J. Oyer, Ph.D.  
Registration No.: 36,628  
Jessamine N. Lee, Ph.D.  
Registration No.: 61,674  
WOLF, GREENFIELD & SACKS, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
617.646.8000